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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,595	02/03/2006	Takeshi Takaha	2005_2066A	3212

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EXAMINER
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SCHMIDTMANN, BAHAR

ART UNIT	PAPER NUMBER
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1623

NOTIFICATION DATE	DELIVERY MODE
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12/17/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/563,595	<b>Applicant(s)</b> TAKAHA ET AL.	
	<b>Examiner</b> BAHAR SCHMIDTMANN	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-15,17,18,20-22,26,27 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 6-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-15,17,18,20-22,26,27 and 30-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 September 2010 has been entered.

This Office Action is in response to Applicant's Amendment and Remarks filed on 16 September 2010 in which claim 5 was canceled and claims 13-15, 18, 20-22 and 30-35 were amended to change the scope and breadth of the claims.

Claims 1-4, 6-15, 17, 18, 20-22, 26, 27 and 30-35 are pending in the current application. Claims 1-4 and 6-12 remain withdrawn as being drawn to a non-elected invention. Claims 13-15, 17, 18, 20-22, 26, 27 and 30-35 are examined on the merits herein.

### ***Withdrawn Rejections***

Applicant's amendment, filed 16 September 2010, with respect to the rejection of claims 13-15, 17, 18, 20-22, 26, 27 and 30-35 under 35 U.S.C. § 112, second paragraph, for indefiniteness, has been fully considered and is persuasive.

Claim 18 has been amended to depend from claim 13.

The recitation "or its modification, or a combination thereof" has been deleted in claims 13-15, 20-22 and 30-35.

The claim as amended more specifically claims the subject matter disclosed and supported in Applicant's Specification.

The rejections are hereby **withdrawn**.

### ***New Rejections***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The recitation "wherein **a** weight ratio of the high molecular weight  $\alpha$ -1,4-glucan and the low molecular weight  $\alpha$ -1,4-glucan..." in instant claim 20, and similarly recited in instant claims 21 and 22, render the claims herein indefinite. The recitation "**a**" implies that there are multiple weight ratios in the independent claim 13, making it unclear which weight ratio is actually being limited or defined herein. This rejection could be overcome by replacing "a" with "the".

### ***Modified Rejections***

The following are new ground(s) or modified rejections necessitated by Applicant's amendment, filed on 16 September 2010, where the limitations in pending claims 13, specifically as amended now have been changed. It should also be noted

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that claims 14, 15, 18, 20-22 and 30-35 have also been amended. Therefore, rejections from the previous Office Action, dated 17 June 2010, have been modified and are listed below.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 13-15, 17, 18, 20-22, 26, 27 and 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hausmanns (WO 02/102355, cited in previous Office Action) in view of Bengs et al. (WO 01/85836 cited in previous Office Action, see US Patent No. 6,908,885 cited in previous Office Action referenced as**

**the English language equivalent of WO 01/85836) as evidenced by IUPAC Gold Book (cited in previous Office Action).**

Hausmanns teaches formation of a molded article (e.g. a hard capsule) from poly(1,4- $\alpha$ -D-glucan) and starch (abstract). Hausmanns teaches the poly(1,4- $\alpha$ -D-glucan) has a degree of polymerization between 40 and 300 (p.3 part c, ii). Hausmanns teaches producing a molded article wherein the poly (1,4- $\alpha$ -D-glucan) is combined with Amyloplast PE 004 potato starch (p.18, example 1), wherein said potato starch (20% unbranched amylose) has a degree of polymerization of 4000 (p. 20, comparative example 2 in table 1), meeting the instant definition of a high molecular weight glucan. Hausmanns teaches the temperature of the aqueous solution of poly (1,4- $\alpha$ -D-glucan) and starch solution was maintained at elevated temperatures, i.e. the temperature was maintained between 50 and 95 °C (p.15, first bullet). Hausmanns teaches the temperature of the first hood was established to cool said aqueous solution of poly(1,4- $\alpha$ -D-glucan) and starch (p.15, second-sixth bullet). Hausmanns teaches the molded article can be used as a pharmaceutical, cosmetic, food, food additive, food supplement and/or food ingredient (p.16).

Hausmanns teaches the molded article is made from a composition comprising 50-95% starch (i.e. the high molecular weight  $\alpha$ -1,4-glucan), more preferably 60-90%, most preferably 70-90% and 5-50% poly(1,4- $\alpha$ -D-glucan) (i.e. the low molecular weight  $\alpha$ -1,4-glucan), more preferably 10-40%, most preferably 10-30% (p.4). Hausmanns also teaches the molded article can be made from at the very least 1% poly(1,4- $\alpha$ -D-glucan) and at the very most 99% starch (claim 1). Hausmanns teaches the poly(1,4- $\alpha$ -D-

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glucan) can be produced enzymatically (p.7) and that the starch can be used with or without chemical modification by esterification and etherification (p.11). Amylopectin is a branched polymer; amylose is unbranched and corresponds to the HMW glucan. The disclosed starch is only 20% amylose.

At the broadest taught range, Hausmanns teaches a ratio of high molecular weight to low molecular weight  $\alpha$ -1,4-glucan ranging from 19.8:1 to 1:5 (i.e. 95% HMW glucan to 5% LMW glucan and 16% HMW glucan to 83% LMW glucan). One having ordinary skill in the art could easily envisage a high molecular weight  $\alpha$ -1,4-glucan to low molecular weight  $\alpha$ -1,4-glucan ratio as 50:50 and 75:25 since these ratios are encompassed by the ranges disclosed by Hausmanns. Furthermore, in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art”, such as the degree of polymerization of the poly(1,4- $\alpha$ -D-glucan), a prima facie case of obviousness exists (see MPEP 2144.05, part I).

Hausmanns does not expressly disclose the molecular weight of the  $\alpha$ -1,4-glucans (all instant claims). However, molecular weight is an inherent property implicitly disclosed in the degree of polymerization. Hausmanns does not expressly disclose the molecular weight distribution of the  $\alpha$ -1,4-glucans (all instant claims). Hausmanns does not expressly disclose neutralizing an alkaline solution (instant claim 15).

The IUPAC Gold Book discloses the degree of polymerization is a number based on the monomeric units in a macromolecule, oligomer molecule, block or chain.

Bengs et al. teaches a gel comprising poly(1,4- $\alpha$ -D-glucan) and starch (abstract). Bengs et al. teaches the polyglucan and starch were prepared either enzymatically or

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chemically, e.g. esterification and/or etherification (column 4, lines 10-19). Bengs et al. also teaches the degree of polymerization of the polyglucan ranges from 40 to 300 (claim 9). Bengs et al. teaches the most preferred polydispersity of the polyglucan as ranging from 1.01 to 2. Bengs et al. also teaches 1.01 to 5 and 1.01 to 2.5. Bengs et al. teaches preparing the glucan composition by neutralizing the alkaline solution (claim 11). Bengs et al. teaches cooling the solution, wherein gel formation occurs after neutralization and during cooling (column 10, lines 29-35). Bengs et al. teaches the gel may be edible, biodegradable, and may additionally comprise active ingredients such as pharmaceutical, cosmetic, agrochemical, odor and/or flavor modifying agents (claim 8).

It would have been obvious at the time the invention was made to prepare a molded article by adding a low molecular weight  $\alpha$ -1,4-glucan to a high molecular weight  $\alpha$ -1,4-glucan.

One having ordinary skill in the art would have been motivated made to prepare a molded article by adding a low molecular weight  $\alpha$ -1,4-glucan to a high molecular weight  $\alpha$ -1,4-glucan because this has been disclosed by Hausmanns. While Hausmanns does not expressly disclose the molecular weight distribution of the  $\alpha$ -1,4-glucans, the taught glucans were prepared enzymatically and/or chemically modified by esterification and/or etherification in a similar process as Bengs et al. and instant application. One having ordinary skill in the art would also be motivated to narrow the polydispersity of the glucans as suggested by Bengs et al., wherein the polydispersity is taught as a broad range of 1.01 to 5, but is preferably limited to the range to 1.01 to 2. The degree of polymerization of the glucans lie within the range and/or overlap with



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instant application, providing additional evidence that the poly(1,4- $\alpha$ -D-glucan) having a lower degree of polymerization is a low molecular weight polymer, while starch having a higher degree of polymerization is a high molecular weight polymer. One having ordinary skill in the art would have been motivated to neutralize and cool the solution to induce gel formation or simply cool the solution to induce gel formation since this is taught by Bengs et al.

Furthermore, molecular weight distribution is a result effective parameter. Because the  $\alpha$ -1,4-glucans disclosed by Hausmanns were prepared in the same manner as Bengs et al. and instantly claimed invention, i.e. enzymatically or chemical modification, one having ordinary skill in the art would know that the molecular weight distribution of the polysaccharides taught by Hausmanns are similar to Bengs et al. which overlaps with the ranges of instantly claimed invention.

Therefore, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

### ***Response to Arguments***

Applicant's amendment and arguments 16 September 2010 have been fully considered but they are not persuasive.

Instant claim 13 has been amended to replace the transitional phrase "comprising" with "consisting essentially of", which is supported by the instant specification. Applicant's instant specification specifically teaches the prior art produces molded articles by mixing low molecular weight  $\alpha$ -1,4-glucans with starch comprising

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high molecular weight  $\alpha$ -1,4-glucan (see p.2, paragraph 0007 to p.7, paragraph 0015 see also p.37, comparative example 2 and 3).

Applicant has argued that the potato starch of Hausmanns is different from the high molecular weight  $\alpha$ -1,4-glucan of the instant claims, because the potato starch of Hausmanns contains about 80% amylopectin. Applicant has argued that amylopectin is a macromolecule material of  $\alpha$ -glucose containing  $\alpha$ -1,4-bonds and  $\alpha$ -1,6-bonds and is a branched molecule.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., **linear**  $\alpha$ -1,4-glucan) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is noted that instant claim 13 has been amended to recite "consisting essentially of". Because amylopectin consists essentially of alpha 1,4-glucan bonds as well, it can be broadly and reasonably interpreted as meeting the limitation of the instant claims. Applicant has repeatedly argued that amylopectin is branched, whereas amylose is linear, however the instant claims do not claim the alpha glucans are linear or branched, just that they consist essentially of alpha 1,4-glucan bonds. The rejection over claim 13 could be overcome by reciting **linear**  $\alpha$ -1,4-glucan, for which there is support in Applicant's specification. The specification discloses examples that consist essentially of the high molecular weight linear  $\alpha$ -1,4-glucan and low molecular weight

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linear  $\alpha$ -1,4-glucan, as well as comparative examples wherein starch is used as a source of high molecular weight  $\alpha$ -1,4-glucan (see p.37, table 2). The instant specification discloses that high molecular weight and low molecular weight *linear*  $\alpha$ -1,4-glucans can be produced enzymatically by the sucrose phosphorylase-glucan phosphorylase method (p.14, paragraph 0050 and 0051; p.35, production examples 1-5, paragraphs 0114-0115). Additionally, the specification recites "1,4-glucan" has straight-chain (p.13, paragraph 0045). However, it should be noted that this does not expressly limit the instantly claimed 1,4-glucans to linear (or straight) polysaccharides, since limitations from the specification cannot be read into the claims.

Independent claims 14 and 15 still recite "comprising", which as discussed in the previous Office Action, is broadly and reasonably met by the combination of starch and  $\alpha$ -1,4-glucan as taught by Hausmanns and Bengs et al. Hausmanns teaches the cooling step in the process for preparing the molded article and Bengs et al. teaches that an alkaline preparatory method can be employed that involves a neutralization and cooling step to induce gel formation.

The rejection is hereby **maintained**.

### ***Conclusion***

In view of the rejections to the pending claims set forth above, no claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. BAHAR SCHMIDTMANN whose telephone number

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is 571-270-1326. The examiner can normally be reached on Mon-Thurs 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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